IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:	Patrick Leahy
Serial Number:	10/596,600
Filed:	April 3, 2007
Title:	"AN ANTI REFLUX SYSTEM"
Group Art Unit:	3774
Examiner:	Michael John Booth
Atty. Docket No.:	3994942--163590

AMENDMENT

Commissioner of Patents
P.O. Box 1450
Alexandria VA 22313-1450

To the Honorable Commissioner:

This Amendment is filed in response to the Office Action mailed February 19, 2010. Please consider the amendments and remarks herein prior to further examination of the above-identified application.

This Amendment includes:

(1) Amendments to the Claims beginning on page 2; and

(2) Remarks beginning on page 5.

Amendments to the Claims:

Please amend the claims as shown in the following Listing of Claims:

1. (**currently amended**) An anti reflux device comprising a valve arranged to allow unidirectional flow through a passage through the valve from an inlet to an outlet; and retention means adapted to enable the device to be secured to a wall of a human or animal stomach, wherein the retention means comprises a flange disposed substantially circumferentially about the valve, which flange comprises a conduit having a plurality of apertures opening onto a stomach ~~contacting~~ contactable side of the flange and through which an adhesive may be pumped onto the stomach ~~contacting~~ contactable side of the flange to provide a layer the adhesive on the stomach contactable side of the flange and enable the device to be secured to the stomach wall, and wherein the plurality of apertures are circumferentially spaced-apart along the flange about the valve.

2. (**original**) A device according to claim 1 wherein the valve is substantially flexible.

3. (**original**) A device according to claim 1 wherein the valve is substantially collapsible.

4. (**original**) A device according to claim 1 wherein the valve comprises a mitral valve.

5. (**cancelled**)

6. (**currently amended**) A device according to claim 1 wherein the flange is provided with an adhesive on the stomach ~~contacting~~ contactable side of the flange.

7. (**cancelled**)

8. (**cancelled**)

9. (**original**) A device according to claim 1 wherein the device is substantially biodegradable.

10. (**original**) A device according to claim 1 wherein the valve is adapted to permit the direction of the flow through the valve to be reversed when a predetermined threshold pressure within the stomach is reached.

11. (**original**) An anti reflux system comprising a device according to claim 1; and positioning means adapted to position the device against the stomach wall while the device is being secured to said stomach wall.

12. (**original**) A system according to claim 11 wherein the positioning means comprises a distensible element adapted to clamp the device between the stomach wall and the distensible element.

13. (**original**) A system according to claim 12 wherein the positioning means comprises a tether detachably engageable with the distensible element, to allow the distensible element to be drawn against the stomach wall.

14. (**original**) A system according to claim 12 wherein the distensible element is an inflatable balloon.

15. (**original**) A system according to claims 11, wherein the retention means comprises a flange disposed substantially circumferentially about the valve, which flange is adapted to enable the device to be secured to the stomach wall; and dispensing means detachably connectable, in fluid communication, with the device, the dispensing means being operable to pump an adhesive onto the flange.

16. (**original**) A system according to claim 11 further comprising insertion means adapted to facilitate the insertion of the device into the stomach.

17. (**original**) A system according to claim 16 wherein the insertion means comprises an elongate tube adapted to receive the device, in a collapsed state, and from which tube the device may be dispensed into the stomach.

18. (**cancelled**)

19. (**cancelled**)

20. (**cancelled**)

21. (**cancelled**)

22. (**cancelled**)

23. (**cancelled**)

24. (**cancelled**)

25. (**new**) A device according to claim 1 wherein the stomach contactable side of the flange and the plurality of apertures face opposite the outlet.

26. (**new**) A device according to claim 25 wherein the flange and conduit are located outside the valve.

27. (**new**) A device according to claim 1 wherein the flange and conduit are located outside the valve.

Remarks:

I. Introduction

In the Office Action mailed on February 19, 2010, the Examiner rejected claims 1 to 4, 6, and 9 to 17. The present amendment cancels no claims, amends claims 1 and 6, and adds new claims 25 to 27. Accordingly, claims 1 to 4, 6, 9 to 17, and 25 to 27 are now pending in this application.

II. Claim Objections

The Examiner objected to claims 1 and 6 because they recite "onto a stomach contacting side" which positively requires the human body. The recitation has been amend to "a stomach contactable side". Reconsideration and withdrawal of the objection is requested.

The Examiner objected to the previous amendment of claim 1 which deletes "substantially" because no support exists in the specification. Applicant respectfully disagrees that the specification does not support the amendment. However, in order to expedite prosecution of the present application. Applicant has reinserted the broader limitation of "substantially circumferentially". Reconsideration and withdrawal of the objection is requested.

The Examiner objected to claim 4 which recites a "mitral valve" which claims a human body part. Applicant respectfully disagrees that the use of the term "mitral valve" claims a human body part. The claim clearly indicates the valve of the device comprises a mitral valve and the term mitral valve is clearly defined in the specification. See paragraph [0032] of the specification. Applicant is confused as to how the examiner can interpreting this claim term as being a human body part. Reconsideration and withdrawal of the objection is requested.

The Examiner objected to claim 15 which recited "substantially circumferentially" which is inconsistent with claim 1. Claim 1 has been amended to remove the inconsistency. Reconsideration and withdrawal of the objection is requested.

III. Claim Rejections based on § 102(b)

The Examiner rejected claims 1 to 3, 6, 9 to 12, and 15 to 17 pursuant to 35. U.S.C. § 102(b) as being anticipated by KIlcoyne et al. (US 6,264,700).

Kilcoyne et al. discloses a valve (20) and a tubular-shaped anchor (18) having a releasable connector (28) secured to a connector (30) of the valve (20). The releasable connector (28) of the anchor (18) has a distal aperture (38). The Examiner indicates that this distal aperture (38) meets the claim limitation of "which flange comprises a conduit having a plurality of apertures opening onto a stomach contactable side of the flange and through which an adhesive may be pumped onto the stomach contactable side of the flange to enable the device to be secured to the stomach wall". Apparently, the examiner is stating that at least two locations along the interior passage of the anchor (18) meets the limitation of "a plurality of apertures". However, even with such a reading, this "plurality of apertures" is not such that adhesive can be pumped through to a stomach contactable side of the flange. In fact, these openings do not even open into the upward facing (in the figures) side of the releasable connector (28) which presumably the Examiner states is contactable with the stomach. Claim 1 has been amended to further point out that the apertures are circumferentially spaced apart on the flange. This is required to pump adhesive about the valve so that it can be secured to the stomach. Kilcoyne et al. clearly does not disclose or suggest such a structure.

Independent claim 1, and claims dependent therefrom, are allowable because they each include the limitations of "wherein the retention means comprises a flange disposed circumferentially about the valve" and "which flange comprises a conduit having a plurality of apertures opening onto a stomach contactable side of the flange and through which an adhesive may be pumped onto the stomach contacting side of the flange to enable the device to be secured to the stomach wall", and "wherein the plurality of apertures are circumferentially spaced-apart along the flange about the valve". No prior art of record reasonably discloses or suggests the present invention as defined by claim 1. Reconsideration and withdrawal of the rejection is requested.

IV. Claim Rejections based on § 103(a)

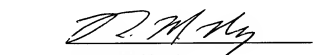
The Examiner rejected claims 4, 13, and 14 pursuant to 35. U.S.C. § 103(a) as unpatentable over KIlcoyne et al. (US 6,264,700) in view of Taylor (US 6,254,642).

Claims 4, 13 and 14 are allowable as depending from allowable claim 1 as discussed above and independently allowable for the novel and nonobvious matter contained therein. Reconsideration and withdrawal of the rejection is requested.

V. Conclusion

In light of the foregoing, it is respectfully submitted that the present application is in a condition for allowance and notice to that effect is hereby requested. If it is found that that the present response does not place the application in a condition for allowance, Applicant's undersigned attorney requests that the Examiner initiate a telephone interview to expedite prosecution of the application. If there are any fees resulting from this communication, please charge same to our Deposit Account No. 50-3915.

Respectfully submitted,



Richard M. Mescher
Reg. No. 38,242

PORTER, WRIGHT, MORRIS & ARTHUR LLP
41 South High Street
Columbus, Ohio 43215
(614) 227-2026
Fax: (614) 227-2100

July 19, 2010